

INVESTIGATOR COMPLIANCE SEARCH FORM

ICON Project Number:	3561-0003 3561-0005	Sponsor Protocol No.:	GLPG1690-CL-203 GLPG1690-CL-301
Principal Investigator Name:	Todd Horiuchi	Address:	Sarasota Memorial Hospital, Clinical Research Center 1540 South Tamiami Trail Sarasota, Florida 34239 United States of America
Medical License Number (if applicable)	ME83060		

Please list all relevant sources of Investigator information, against which this Investigator has been checked.

SOURCE #	SOURCE NAME	SOURCE DATE	WEBLINK	ISSUES ID	ENTIFIED
1.	FDA DEBARMENT LIST	30 Oct 2017	http://www.fda.gov/ora/complianceref/debar/default.htm	⊠ No	☐ Yes
2.	CLINICAL INVESTIGATOR INSPECTION LIST (CLIIL) (CDER)	29 Jun 2017	http://www.accessdata.fda.gov/scripts/cder/cliil/index.cfm	⊠ No	☐ Yes
3.	FDA WARNING LETTERS and RESPONSES	07 Nov 2017	http://www.fda.gov/ICECl/EnforcementActions/WarningLetters/default.htm	⊠ No	☐ Yes
4.	NOTICE OF OPPORTUNITY FOR HEARING (NOOH) – PROPOSAL TO DEBAR	07 Aug 2017	http://www.fda.gov/Regulatorylnformation/FOl/ElectronicReadingRoom/ucm143240.htm	⊠ No	☐ Yes
5.	ADEQUATE ASSURANCES LIST FOR CLINICAL INVESTIGATORS	24 Apr 2014	http://www.fda.gov/ora/complianceref/bimo/asurlist.htm	⊠ No	☐ Yes
6.	CLINICAL INVESTIGATORS — DISQUALIFICATION PROCEEDINGS (FDA DISQUALIFIED/RESTR ICTED)	17 Jul 2017	http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true	⊠ No	☐ Yes
7.	PHS Administrative Actions Listing	07 Nov 2017	http://ori.hhs.gov/misconduct/A dminBulletinBoard.shtml	⊠ No	☐ Yes
8.	Clinical Investigator Inspection List (CBER)	10 Oct 2017	http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm	⊠ No	☐ Yes
9.	HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD	04 Oct 2017	http://exclusions.oig.hhs.gov/	⊠ No	☐ Yes
10.	HHS/OIG Corporate Integrity Agreements/Watch List	01 Nov 2017	http://oig.hhs.gov/compliance/corporate-integrity-agreements/ciadocuments.asp	⊠ No	☐ Yes
11.	SAWSYSTEM FOR AWARD MANAGEMENT	02 Nov 2017	https://www.sam.gov/portal/public/SAM	⊠ No	☐ Yes



12.	LIST OF SPECIALLY DESIGNATED NATIONALS	01 Nov 2017	http://www.treasury.gov/resour ce-center/sanctions/SDN- List/Pages/default.aspx	⊠ No	☐ Yes
13.	World Check (Only for PI)	02 Nov 2017	http://www.truthtechnologies.com/	⊠ No	☐ Yes

If issues are identified (Yes checked above), please provide additional details. Details may be printed and attached.

SOURCE	DATE OF					
#	INSPECTION/	DESCRIPTION OF FINDINGS				
#	ACTION					
NA	NA	World Check was performed for the institute Sarasota Memorial Hospital, Clinical Research Center on 02 November 2017				
	02 November 2017					
Institute World Check	Sarasota Memorial Hospital, Clinical Research Center	Dec 2015 – agreed to pay USD972,000 to settle False Claims act allegations pertaining to minimally-invasive kyphoplasty procedures.				
Institute World check Finding						
	12 February 2016	Taken By: HAWAII MEDICAL BOARD				
ML	Todd Horiuchi	Date Of Action: 12 February 2016				
	ML # ME83060	Description of Disciplinary Action: REPRIMAND				
	Disciplinary Action	Under Appeal: No				
	07 January 2016	Date of Suit: 25 March 2014				
ML	Todd Horiuchi ML # ME83060	Date of Final Disposition: 09 January 2015				
IVIL	Claim # 13-0067-B- 12	Indemnity Paid: \$32,500				
	Malpractice Claim	Claim issue: Alleged Achilles tendon tear				

Search Performed By:

Printed		_
Name:	Signature:	Date:

Jegan Vaidyanathan

Jegan Vaidyanathan 09 Nov 2017 09:15:052+0000

REASON: I approve this document as author.

de3376c0-88d1-42f6-938c-e66145a5574e

Customer

?,? Citizenship DOB

"Sarasota Memorial Hospital

Internal Reference Note:

ID

Ran By: Paras Doshi Ran On: Nov 02, 2017 06:10 AM

Annotations

Matching Names

SARASOTA MEMORIAL HOSPITAL,

Data Source: World-Check

Result Type: Reviewed - Match Original Result Type: Medium Risk

Verified (Accepted)

Score: 100 Search Type: Entity

Last Updated By: Paras Doshi Last Updated On: November 7, 2017 12:00 AM

Category: CORPORATE Sub-Category:

Listed On: 2015/12/21 Updated On: Source Reference 2896673

ID:

Citizenship	USA
Data Source	USDOJ
Additional Information	[BIOGRAPHY] To be determined. [IDENTIFICATION] To be determined. [REPORTS] Dec 2015 - agreed to pay USD972,000 to settle False Claims act allegations pertaining to minimally-invasive kyphoplasty procedures.
Entity Type	E
Locations person is active in	
~Sarasota, Florida~ USA	
External Link	http://www.justice.gov/usao-wdny/pr/32-hospitals-pay-us-more-28-million-resolve-false-claims-act-allegations-related



TODD KEN HORIUCHI

License Number: ME83060

Data As Of 11/9/2017

ProfessionMedical DoctorLicenseME83060License StatusCLEAR/ACTIVELicense Expiration Date1/31/2018License Original Issue Date07/27/2001

Address of Record 1843 FLOYD STREET
SARASOTA, FL 34239
UNITED STATES

Controlled Substance Prescriber (for the Treatment of Chronic Non-malignant Pain)YesDiscipline on FileNoPublic ComplaintNo

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.



TODD KEN HORIUCHI

License Number<mark>: ME8306</mark>0

Profession Medical Doctor

License Status CLEAR/ACTIVE

Year Began Practicing Not Provided

License Expiration Date 01/31/2018

Controlled Substance Yes

Prescriber (for the Treatment of Chronic Non-malignant Pain)

Information in this profile has been verified by the practitioner.

Primary Practice Address

TODD KEN HORIUCHI 1843 FLOYD STREET SARASOTA, FL 34239 UNITED STATES

Medicaid

This practitioner does NOT participate in the Medicaid program.

Staff Privileges

This practitioner currently holds staff privileges at the following hospital/medical/health institutions:

Institution Name	City	State
SARASOTA MEMORIAL HOSPITAL	SARASOTA	FI ORIDA

Email Address

Please contact at: sharon@h2md.com

Other State Licenses

This practitioner has indicated the following additional state licensure:

State	Profession
HAWAII	MEDICAL DOCTOR

Information in this profile has been verified by the practitioner.

Education and Training

Institution Name	Degree Title	Dates of Attendance	Graduation Date
WASHINGTON UNIVERSITY	MD	8/1/1991 - 5/19/1995	05/19/1995

Other Health Related Degrees

This practitioner has completed the following other health related degrees:

School/University	City	State/Country	Dates Attended From	Dates Attended To	Degree Title
WASHINGTON UNIVERSITY	ST. LOUIS	MISSOURI	08/01/1987	05/01/1991	BA - BIOLOGY

Professional and Postgraduate Training

This practitioner has completed the following graduate medical education:

Program Name	Program Type	Specialty Area	Other Specialty Area	City	State or Country	Dates Attended From	Dates Attended To
UNIVERSITY OF TEXAS	RESIDENCY	IM - INTERNAL MEDICINE		DALLAS	TEXAS	07/01/1995	06/30/1998
WASHINGTON UNIVERSITY	FELLOWSHIF	P IM - PULMONARY DISEASE AND CRITICAL CARE		ST. LOUIS	MISSOURI	07/01/1998	01/01/0001

Information in this profile has been verified by the practitioner.

Academic Appointments

11/9/2017 FL DOH MQA Search Portal |

This practitioner does not currently hold faculty appointments at any medical/health related institutions of higher learning.

Specialty Certification

This practitioner holds the following certifications from specialty boards recognized by the Florida board which regulates the profession for which he/she is licensed:

Specialty Board Certification

AMERICAN BOARD OF INTERNAL MEDICINE IM - PULMONARY DISEASE

Financial Responsibility

I have hospital staff privileges or I perform surgery at an ambulatory surgical center and I have professional liability coverage in an amount not less than \$250,000 per claim, with a minimum annual aggregate of not less than \$750,000 from an authorized insurer as defined under s. 624.09, F. S., from a surplus lines insurer as defined under s. 626.914(2), F. S., from a risk retention group as defined under s. 627.942, F.S., from the Joint Underwriting Association established under s. 627.351(4), F. S., or through a plan of self-insurance as provided in s.627.357, F.S.

Information in this profile has been verified by the practitioner.

Proceedings & Actions

Criminal Offenses

The criminal history information, if any exists, may be incomplete; federal criminal history information is not available to the public. Information is verified by the Department at the time of initial licensure and renewal.

This practitioner has indicated that he/she has no criminal offenses required to be published on this profile.

Medicaid Sanctions and Terminations

This practitioner has not been sanctioned or terminated for cause from the Medicaid program.

Final Disciplinary Actions Reported by the Department of Health within the last 10 years:

The information below is self reported by the practitioner.

Final disciplinary action taken by a specialty board within the last 10 years:

This practitioner has indicated that he/she has *NOT* had any final disciplinary action taken against him/her within the last 10 years by a specialty board.

Final disciplinary action taken by a licensing agency within the last 10 years:

This practitioner has indicated that he/she has had final disciplinary action taken against him/her within the last 10 years by a licensing agency.

Taken By	Date Of Action	Description of Disciplinary Action	Under Appeal
HAWAII MEDICAL BOARD	02/12/2016	REPRIMAND	NO

Disciplinary action taken by a health maintenance organization, pre-paid health clinic, nursing home, hospital or ambulatory surgical center within the last 10 years:

This practitioner has indicated that he/she has *NOT* had any final disciplinary action taken against him/her within the last 10 years by a health maintenance organization, pre-paid health clinic, nursing home, hospital or ambulatory surgical center.

The following discipline has been reported as required under 456.041(5), F.S. within the previous 10 years.

Resignation from or non-renewal of medical staff membership or the restriction or revocation of staff privileges within the last 10 years by a health maintenance organization, pre-paid health clinic, nursing home, hospital or ambulatory surgical center in lieu of or in settlement of a pending disciplinary case related to competence or character.

This practitioner has indicated that he/she has *NEVER* been asked to or allowed to resign from or had any medical staff privileges restricted or revoked within the last 10 years by a health maintenance organization, pre-paid health clinic, nursing home, hospital or ambulatory surgical center.

Liability Claims Exceeding \$100,000.00 Within last 10 years.

Settlement of a claim may occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the physician. A payment settlement of a medical malpractice action or claim should not be construed as creating a presumption that medical malpractice has occurred.

Additional claims information may have been reported to the Department of Financial Services. To check their web site, please click here.

There have not been any reported liability actions, which are required to be reported under section 456.049, F. S., within the previous 10 years.

Information in this profile has been verified by the practitioner.

Committees/Memberships

This practitioner has not indicated any committees on which they serve for any health entity with which they are affiliated.

Professional or Community Service Awards

This practitioner has not provided any professional or community service activities, honors, or awards.

Publications

This practitioner has not provided any publications that he/she authored in peer-reviewed medical literature within the last ten years.

Professional Web Page

H2MD.com

Languages Other Than English

This practitioner has not indicated that any languages other than English are used to communicate with patients, or that any translation service is available for patients, at his/her primary place of practice.

Other Affiliations

This practitioner has not provided any national, state, local, county, or professional affiliations.

11/9/2017 M201573410

Florida Office of Insurance Regulation Medical Malpractice Closed Claims Report

Department File Number: M201573410
Claim Number: 13-0067-B-12
Date Submitted: 1/7/2016

Insurer Information

Insurer Name Coverage Type

FD INSURANCE COMPANY Primary

Insurer FEIN Professional License Number

20-3704679

Insurer Contact Information

TypeFirst NameMILast NameIndividualTamlaLloyd

Street Address

4651 Salisbury Road, Suite 410

CityStateZipJacksonvilleFL32256

Phone Ext Fax E-Mail Address

(904) 296 - 2887 212 (904) 296 - 1245 tlloyd@fdinsurancecompany.com

Insured Information

TypeFirst NameMILast NameIndividualToddHoriuchi

Insurer TypeStreet Address of PracticeLicensed2130 S. Tamiami Trail

CityStateZip CodeCountySarasotaFL34239Sarasota

Policy Number Per Claim Policy Limits Aggregate Policy Limits

12015 \$250,000 \$750,000

Profession or Business Other Profession or Business

Medical Doctor

License Number Specialty Code & Classification

License Number Specialty Code & Classification Certification Number

ME83060 Internal Medicine - No Surgery

11/9/2017 M201573410

Florida Office of Insurance Regulation Medical Malpractice Closed Claims Report

Sarasota

Injured Person Information

First Name MI Last Name Date of Birth

Street Address Gender County where Injury Occurred

M

City State Zip Code

Location where injury occured Other location where injury occured

Physician's Office

Location of Institutional Injury

Other Location of Institutional Injury

Other Physician's Office

Date of Occurrence Date Reported to Insurer

12/22/2012 3/6/2013

Diagnostic Information

Final Diagnosis For Which Treatment Was Sought Including Patient's Actual Condition

Patient was presented on 12/19/12 with cough and again on 12/22/12 with chest congestion.

Operation, Diagnostic, Or Treatment Procedure Rendered Causing The Injury

None shown

Diagnostic Code:

Misdiagnosis Made, If Any, Of Patient's Actual Condition

None made

Principal Injury Giving Rise To The Claim

Alleged Achilles tendon tear

Severity Of Injury

Temporary: Minor - Infections, misset fracture, fall in hospital. Recovery delayed.

M201573410 11/9/2017

Florida Office of Insurance Regulation **Medical Malpractice Closed Claims Report**

Legal Information

Circuit Court Case Number Date of Suit

2014-CA-001685 3/25/2014

Date of Final Disposition County Suit Filed in

1/9/2015 Sarasota

Other Defendants Involved in this Claim

Hautamaki, Raymond R. Dean Hautamaki, MD, PA Todd K. Hortuchi, MD, LLC Hautamaki & Horiuchi, LLC

Stage of Legal System at which Settlement was Reached or Award Made

More than 90 days, after suit filed and prior to or during the course of mandatory settlement conference.

Final Method of Claim Disposition

Settled by parties

Court Decision Other

No Court Proceedings.

Arbitration

Claim not subject to Arbitration.

Date of Payment

1/9/2015

Financial Information

Was there a settlement Resulting in payment to the Plaintiff?

Indemnity Paid by Insurer on behalf of Insured **Loss Adjust Expense Paid to Defense Counsel**

All Other Loss Adjustment Expense Paid **Injured Person's Total Non-Economic Loss** Deductible

Injured Person's Total Economic Loss

Incurred to Date **Anticipated Medical Expense** \$0 \$0 Wage Loss \$0 \$0 Other Expenses \$0

Safety Management Steps Taken by Insured to Make Similar Occurrence Less Likely

Circumstances of this case have been discussed with insured and Risk Management was notified. Risk management has discussed with insured.

Updates

Date of Change: 2/13/2015 10:29:32 AM

Reason for Change: Added Loss Adjusted/Counsel amount.

Field Changed Former Value **New Value** 15414

Amount of Loss Adjustment Expense Paid to Defense Counsel

1/7/2016 2:29:40 PM Date of Change: Reason for Change: Updated Final LAE.

New Value Field Changed Former Value

Amount of Loss Adjustment Expense Paid to Defense Counsel 15414 20766 Yes

\$32,500

\$20,766